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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/446,298 | 06/12/2000 | DIETER LUBDA | MERCK2047 | 2130 |

7590 08/14/2002

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EXAMINER

ROCHE, LEANNA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1771

12

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

mk-12

Office Action Summary

| | | |
|-------------------------------|------------------------------|--|
| Application No. 09/446,298 | Applicant(s) LUBDA ET AL. | |
| Examiner Leanna Roche | Art Unit 1771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 04 February 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Claims 1, 2 and 4 in Paper No. 11 is acknowledged. Claims 3 and 5-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.
2. The traversal is on the ground(s) that the restriction set forth in the Office Action is not proper because it does not conform to the practice set forth in MPEP 806.05 (i). This is not found persuasive because as set forth in MPEP 1850, "when the Office considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111." Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.
3. In the present case, a monolithic sorbent surrounded in a liquid-impermeable manner by a pressure-resistant plastic casing is the special technical feature of the invention. It is the examiner's position that WO 94/19687 either anticipates or makes

obvious this claimed special technical feature. Therefore, the claimed special technical feature at present does not presently make a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/19687.

WO 94/19687 teaches a chromatography pillar comprised of a porous ceramic molded body surrounded by an impermeable Teflon material (Page 7 and Figure 1). The porous ceramic molded body of WO 94/19687 reads on Applicant's encased monolithic sorbent comprising a porous ceramic molding. The impermeable Teflon material of WO 94/19687 reads on Applicant's liquid-impermeable, pressure-resistant plastic casing because it is known in the art of chromatography that Teflon is pressure resistant (see USPN 4556538, Column 2, lines 25-31).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/19687 as applied to claim 1 above, and further in view of Nakanishi et al. (USPN 5624875).

WO 94/19687 teaches an encased monolithic sorbent which may have varied pore size distribution, but does not specifically teach that their porous ceramic molding has interconnected macropores with mesopores in the walls of the macropores, the diameter of the macropores being greater than 0.1 μm and the diameter of the mesopores ranging from 2 to 100 nm. Nakanishi is directed to inorganic porous materials for producing columns for chromatography, the inorganic porous material having interconnected continuous macropores with a median diameter greater than 0.1 μm and having mesopores in the walls of the macropores, the median diameter of the mesopores ranging from 2 to 100 nm. Nakanishi states that their inorganic porous material solves various problems with conventional inorganic packed columns, such as long analysis times, low flow rates, and scattered analysis results from multiple columns. It would have been obvious to the skilled artisan at the time this invention was made to use the inorganic porous material of Nakanishi in the chromatographic pillar of WO 94/19687, motivated by the desire to produce a chromatographic column with shorter analysis times, higher flow rates and greater reproducibility of results from multiple columns.

Response to Arguments

8. The information disclosure statement filed February 4, 2002 provides sufficient information for the consideration of CH 507724, which is indicated on Paper No. 9. With regard to the incorporation of material by reference, Applicant's arguments are sufficient to overcome the previous objection to the disclosure. However, the examiner kindly requests that Applicant provide copies of *Anal. Chem.* **64** (1992), pp. 820-822 and *J. Chromatogr.* **473** (1989), pp. 273-275, so that the application record is complete. The informal drawings filed February 4, 2002 are sufficient to overcome the previous objection to the specification requiring the incorporation of drawings. Applicant's amendments to Claims 2 and 3 are sufficient to overcome the previous rejections under 35 USC 112, second paragraph and 35 USC 101.

9. Applicant's arguments with respect to claims 1, 2 and 4 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1771

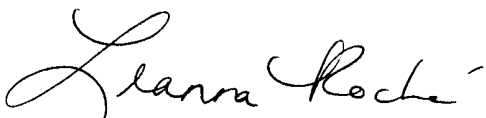
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

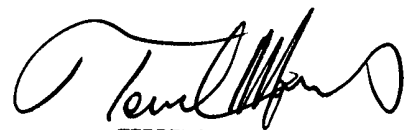
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leanna Roche whose telephone number is 703-308-6549. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm (with alternate Mondays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



lmr
August 7, 2002



TERREL MORRIS
SUPERVISORY PATENT EXAMINER
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